



8 0300

Dkt. 62164/JPW/PJP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Xin Qu & Judah Z. Weinberger
Serial No. : 09/657,701
Filed : September 8, 2000
For : MODIFICATION OF POLYMER SURFACES AS
RADIOISOTOPE CARRIERS

1185 Avenue of the Americas
New York, New York 10036
August 13, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

INFORMATION DISCLOSURE STATEMENT

In compliance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following references, which are listed on the accompanying form PTO-1449 (Exhibit 1). Copies of references 1-28 attached hereto as Exhibits 2-22 respectively, except for reference numbers 3, 14, 16, 17, 21, 24 and 25.

U.S. Patent Documents

1. U.S. Patent No. 5,762,903 to Park et al. (Exhibit 2)

Foreign Patent Documents

2. Foreign Patent No. WO 9917812 (Exhibit 3);

Applicants : Xin Qu & Judah Z. Weinberger
Serial No. : 09/657,701
Filed : September 8, 2000
Page 2

Other Documents

3. Gruentzig AR, King SB, Schlumpf M, et al. Long-term follow-up after percutaneous transluminal coronary angioplasty. *N Engl J Med* 1987;316:1127-32 (Exhibit 4);
4. Nobuyoshi M, Kimura T, Nosaka H, et al. Restenosis after successful percutaneous transluminal coronary angioplasty: serial angiographic follow-up of 229 patients. *J Am Coll Cardiol* 1988;12:616-23 (Exhibit 5);
5. Muller DWM, Ellis SG, Topol EJ. Colchicine and antineoplastic therapy for prevention of restenosis after percutaneous coronary interventions. *J Am Coll Cardiol* 1991;17:26B-31B;
6. Urban P, Buller N, Fox K, et al. Lack of effect of warfarin on the restenosis rate or on clinical outcome after balloon coronary angioplasty. *Br Heart J* 1988;60:485-8 (Exhibit 6);
7. Wiedermann JG, Marboe C, Amols H, Schwartz A, Weinberger J. Intracoronary irradiation markedly reduces restenosis after balloon angioplasty in a porcine model. *JACC* 1994;23(6):1491-8 (Exhibit 7);
8. Wiedermann JG, Marboe C, Amols H, Schwartz A, Weinberger J. Intracoronary irradiation markedly reduces neointimal proliferation after balloon angioplasty in swine: persistent benefit at 6-month follow-up. *JACC* 1994;25(6):1451-6 (Exhibit 8);
9. Mazur W, Ali MN, Khan MM, Dabaghi SF, DeFelice CA, Paradis JP, Butler EBA, Wright E, Fajardo LFB, French A and Raizner AE. High dose rate intracoronary radiation for inhibition of neointimal formation in the stented and balloon-injured porcine models of restenosis: Angiographic, morphometric,

Applicants : Xin Qu & Judah Z. Weinberger
Serial No. : 09/657,701
Filed : September 8, 2000

and histopathologic analysis. Int J Rad Onc Biol Phys 1996;
36(4):777-788 (Exhibit 9);

10. Waksman R, Robinson KA, Crocker IR, Gravanis MB, Cipolla GD, and King SR. Endovascular low-dose irradiation inhibits neointima formation after coronary artery balloon injury in swine: A possible role for radiation therapy in restenosis prevention. Circulation 1995;91(5):1533-9 (Exhibit 10);
11. Verin V, Popowski Y, Urban P, et al. Intra-arterial beta irradiation prevents neointimal hyperplasia in a hypercholesterolemic rabbit restenosis model. Circulation 1995;92:2284-90 (Exhibit 11);
12. Condado JA, Waksman R, Gurdie O, et al. Long-term angiographic and clinical outcome after percutaneous transluminal coronary angioplasty and intracoronary radiation therapy in humans. Circulation 1997;96:727-32 (Exhibit 12);
13. Teirstein PS, Massullo V, Jani S, et al. Catheter-based radiotherapy to inhibit stenosis after coronary stenting. N Engl J Med 1997; 336:1697-703 (Exhibit 13);
14. Verin V, Urban P, Popowski Y, et al. Feasibility of intracoronary B-irradiation to reduce restenosis after balloon angioplasty, a clinical pilot study. Circulation 1997;95:1138-44 (Exhibit 14);
15. Weinberger J. Intracoronary radiation using radioisotope solution-filled balloons. Herz 1998;23:366-72 (Exhibit 15);

Applicants : Xin Qu & Judah Z. Weinberger
Serial No. : 09/657,701
Filed : September 8, 2000

16. Muzzarelli RAA. Chitin. Pergamon, Oxford 1977;
17. Guibal E. Dambies L, Milot C, Roussy J. Influence of polymer structural parameters and experimental conditions on metal anion sorption by chitosan. Polym Intern 1999;48(8):671-80 (Exhibit 16);
18. Nishimura Y, Katuta I, Takeda H, et al. Effect of natural chelating agents on the intestinal-absorption of radiostrontium in rats. Radiation Protection Dosimetry 1994;53 (1-4):331-34;
19. Park KB, Kim YM, Kim JR. Radioactive chitosan complex for radiation therapy U.S. Patent No. 5,762,903;
20. Qu X, Weinberger J. Novel B-emitting poly(ethylene terephthalate) surface modification. J Biomed Material Research In press (Exhibit 17);
21. Qu X, Wirsen A, Albertsson AC. Structural change and swelling mechanism of pH-sensitive hydrogels based on chitosan and D, L-lactic acid. J Appl Polym Sci 1999;74(13):3186-92 (Exhibit 18);
22. Qu X, Wirsen A, Albertsson AC. Synthesis and characterization of pH-sensitive hydrogels based on chitosan and D, L-lactic acid. J Appl Polym Sci 1997;74(13):3193-02 (Exhibit 19);
23. Rochery M, Lam TM, Crighton JS. FTIR&ATR analyses on a polypropylene (PP) surface after plasma treatment in the study of chitosan surface grafting to improve PP dyeing behavior. Macromol symp 1997; 119:277-82;

Applicants : **Xin Qu & Judah Z. Weinberger**
Serial No. : **09/657,701**
Filed : **September 8, 2000**

24. Pioletti DP, Takei H, Lin T, et al. The effect of calcium phosphate cement particles on osteoblast functions. *Biomaterials* 2000;21:1103-14 (Exhibit 20);
25. Varma HK, Yokogawa Y, Espinosa FF, et al. Porous calcium phosphate coating over phosphorylated chitosan film by a biomimetic method. *Biomaterials* 1999;20:879-84 (Exhibit 21);
26. Lewis RE, Tercho GP, Walsh PR. Intra-coronary radiation devices containing Ce-144 or Ru-106. PCT Publication No. WO 99/17812;
27. Roberts GAF, Chitin Chemistry, Macmillan, Houndsills 1992; and
28. Zamora PO, Osakis, Som P, Ferretti JA, Choi JS, Hu C, Tsang R, Kuan HM, Singletary S, Stern R A, Oster ZH, Radiolabeling Brachytherapy Sources with Re-188 through Chelating Microfilms: Stents, *Journal of Biomedical Materials Research*, Vol 53, No. 4 pp 244-251 (May 11, 2000) (Exhibit 22);

Applicants believe that these references do not anticipate or render obvious applicants' claimed invention.

Because this Information Disclosure Statement is being submitted before the mailing of a first Office Action on the merits, no fee is believed to be due. However, in the event that a first Office Action on the merits has been mailed which has not yet reached

Applicants : Xin Qu & Judah Z. Weinberger
Serial No. : 09/657,701
Filed : September 8, 2000

applicant's attorney, or has not yet been connected to the file in applicant's attorney's office, applicant hereby requests for consideration of this Information Disclosure Statement, pursuant to 37 C.F.R. §1.97(c) and authorize the Office to Charge Deposit Account No. 03-3125 the amount of the petition fee in accordance with 37 C.F.R. §1.17(p). In the event that a Notice of Allowance has been mailed, applicant hereby petitions, pursuant to 37 C.F.R. §1.97(d), for consideration of this Information Disclosure Statement, and authorize the Office to charge Deposit Account No. 03-3125 the amount of the fee in accordance with 37 C.F.R. §1.17(i).

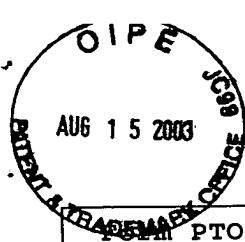
Respectfully submitted,

John P. White
Registration No. 28,678
Peter J. Phillips
Registration No. 29,691
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Peter J. Phillips 8/13/03
Peter J. Phillips Date
Reg. No. 29,691



AUG 15 2003

Sheet 1 of 4

TRADEMARK PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 0575-62164/JPW/PJP	Serial No. 09/657,701
		Applicants Xin Qu & Judah Z. Weinberger	
		Filing Date September 8, 2000	Group

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	C	Gruentzig AR, King SB, Schlumpf M, et al. Long-term follow-up after percutaneous transluminal coronary angioplasty. <i>N Engl J Med</i> 1987;316:1127-32 (Exhibit 4);
	D	Nobuyoshi M, Kimura T, Nosaka H, et al. Restenosis after successful percutaneous transluminal coronary angioplasty: serial angiographic follow-up of 229 patients. <i>J Am Coll Cardiol</i> 1988;12:616-23 (Exhibit 5);
	E	Muller DWM, Ellis SG, Topol EJ. Colchicine and antineoplastic therapy for prevention of restenosis after percutaneous coronary interventions. <i>J Am Coll Cardiol</i> 1991;17:26B-31B;

Examiner _____ **DATE CONSIDERED** _____

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this from with next communication to applicant.



AUG 15 2003

U.S. PATENT AND TRADEMARK OFFICE

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No. Serial No.
0575-62164/JPW/PJP 09/657,701LIST OF PRIOR ART CITED BY APPLICANT
(Use several sheets if necessary)Applicants
Xin Qu & Judah Z. WeinbergerFiling Date Group
September 8, 2000

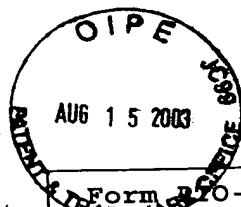
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	F	Urban P, Buller N, Fox K, et al. Lack of effect of warfarin on the restenosis rate or on clinical outcome after balloon coronary angioplasty. Br Heart J 1988;60:485-8 (Exhibit 6);
	G	Wiedermann JG, Marboe C, Amols H, Schwartz A, Weinberger J. Intracoronary irradiation markedly reduces restenosis after balloon angioplasty in a porcine model. JACC 1994;23(6):1491-8 (Exhibit 7);
	H	Wiedermann JG, Marboe C, Amols H, Schwartz A, Weinberger J. Intracoronary irradiation markedly reduces neointimal proliferation after balloon angioplasty in swine: persistent benefit at 6-month follow-up. JACC 1994;25(6):1451-6 (Exhibit 8);
	I	Mazur W, Ali MN, Khan MM, Dabaghi SF, DeFelice CA, Paradis JP, Butler EBA, Wright E, Fajardo LFB, French A and Raizner AE. High dose rate intracoronary radiation for inhibition of neointimal formation in the stented and balloon-injured porcine models of restenosis: Angiographic, morphometric, and histopathologic analysis. Int J Rad Onc Biol Phys 1996; 36(4):777-788 (Exhibit 9);
	J	Waksman R, Robinson KA, Crocker IR, Gravanis MB, Cipolla GD, and King SR. Endovascular low-dose irradiation inhibits neointima formation after coronary artery balloon injury in swine: A possible role for radiation therapy in restenosis prevention. Circulation 1995;91(5):1533-9 (Exhibit 10);
	K	Verin V, Popowski Y, Urban P, et al. Intra-arterial beta irradiation prevents neointimal hyperplasia in a hypercholesterolemic rabbit restenosis model. Circulation 1995;92:2284-90 (Exhibit 11);
	L	Condado JA, Waksman R, Gurdie O, et al. Long-term angiographic and clinical outcome after percutaneous transluminal coronary angioplasty and intracoronary radiation therapy in humans. Circulation 1997;96:727-32 (Exhibit 12);

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this from with next communication to applicant.



Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeLIST OF PRIOR ART CITED BY APPLICANT
(Use several sheets if necessary)

Atty. Docket No. 0575-62164/JPW/PJP Serial No. 09/657,701

Applicants
Xin Qu & Judah Z. Weinberger

Filing Date September 8, 2000 Group

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

M Teirstein PS, Massullo V, Jani S, et al. Catheter-based radiotherapy to inhibit stenosis after coronary stenting. N Engl J Med 1997;336:1697-703 (Exhibit 13);

N Verin V, Urban P, Popowski Y, et al. Feasibility of intracoronary B-irradiation to reduce restenosis after balloon angioplasty, a clinical pilot study. Circulation 1997;95:1138-44 (Exhibit 14);

O Weinberger J. Intracoronary radiation using radioisotope solution filled balloons. Herz 1998;23:366-72 (Exhibit 15);

P Mazzarelli RAA. Chitin. Pergamon, Oxford 1977;

Q Guibal E, Dambies L, Milot C, Roussy J. Influence of polymer structural parameters and experimental conditions on metal anion sorption by chitosan. Polym Intern 1999;48(8):671-80 (Exhibit 16);

R Nishimura Y, Katuta I, Takeda H, et al. Effect of natural chelating agents on the intestinal-absorption of radiostrontium in rats. Radiation Protection Dosimetry 1994;53 (1-4):331-34;

S Park KB, Kim YM, Kim JR. Radioactive chitosan complex for radiation therapy U.S. Patent No. 5,762,903;

T Qu X, Weinberger J. Novel B-emitting poly(ethylene terephthalate) surface modification. J Biomed Material Research In press (Exhibit 17);

U Qu X, Wirsén A, Albertsson AC. Structural change and swelling mechanism of pH-sensitive hydrogels based on chitosan and D, L-lactic acid. J Appl Polym Sci 1999;74(13):3186-92 (Exhibit 18);

V Qu X, Wirsén A, Albertsson AC. Synthesis and characterization of pH-sensitive hydrogels based on chitosan and D, L-lactic acid. J Appl Polym Sci 1997;74(13):3193-02 (Exhibit 19);

W Rochery M, Lam TM, Crighton JS. FTIR&ATR analyses on a polypropylene (PP) surface after plasma treatment in the study of chitosan surface grafting to improve PP dyeing behavior. Macromol Symp 1997; 119:277-82;

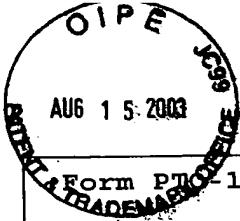
X Pioletti DP, Takei H, Lin T, et al. The effect of calcium phosphate cement particles on osteoblast functions. Biomaterials 2000;21:1103-14 (Exhibit 20);

Y Varma HK, Yokogawa Y, Espinosa FF, et al. Porous calcium phosphate coating over phosphorylated chitosan film by a biomimetic method. Biomaterials 1999;20:879-84 (Exhibit 21);

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



AUG 15 2003

Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 0575-62164/JPW/PJP	Serial No. 09/657,701
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				Applicants Xin Qu & Judah Z. Weinberger	
				Filing Date September 8, 2000	Group
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
Z	Lewis RE, Tercho GP, Walsh PR. Intra-coronary radiation devices containing Ce-144 or Ru-106. PCT Publication No. WO 99/17812;				
AA	Roberts GAF, Chitin Chemistry, Macmillan, Hounds mills 1992; and				
BB	Zamora PO, Osakis, Som P, Ferretti JA, Choi JS, Hu C, Tsang R, Kuan HM, Singletary S, Stern R A, Oster ZH, Radiolabeling Brachytherapy Sources with Re-188 through Chelating Microfilms: Stents, Journal of Biomedical Materials Research, Vol 53, No. 4 pp 244-251 (May 11, 2000) (Exhibit 22);				
EXAMINER		DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this from with next communication to applicant.